UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

UNITED STATES OF AMERICA	*	**CRIMINAL ACTION NO. 2:17 -CR-00039**
	*	
v.	*	
	*	**JUDGE WALTER**
KOHLL'S PHARMACY AND HOMECARE INC., ET AL.	*	
	*	
	*	**MAGISTRATE JUDGE KAY**
	*	
	*	

****

MEMORANDUM ORDER

Before the court are a Motion to Dismiss (Rec. Doc. 36) counts 1, 2, and 4 of the indictment, filed by Kohll's Pharmacy and Homecare, Inc. d/b/a/ Essential Pharmacy Compounding ("EPC"), and a Motion to Dismiss (Rec. Doc. 37) counts 1, 3, 5, and 6 of the indictment, filed by Kyle James Hebert. The defendants allege that the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C.A § 301, *et seq.*, does not apply to veterinarian compounding or, in the alternative, that a veterinarian compounded prescription is not a "new drug" under the FDCA. The government opposes the motions. (Rec. Doc. 44). For the following reasons, the court **DENIES** the Motions to Dismiss the Indictment (Rec. Docs. 36, 37).

I. FACTS & PROCEDURAL HISTORY

EPC is located in Omaha, Nebraska, and it sells animal drugs to veterinarians.[1] Hebert is a Louisiana licensed veterinarian, who specializes in the treatment of racehorses.[2] Between 2010 and 2012, EPC and Hebert allegedly worked together to provide a synthetic version of dermorphin to racehorses to influence the outcome of the races.[3] Dermorphin allegedly made the

[1] Indictment (Rec. Doc. 1), ¶ A.2. ¶ A.7.D.

[2] *Id.* ¶ A.1.

[3] *Id.* ¶ B.

racehorses more focused and run faster.[4] No drug containing dermorphin has been approved by the United States Food and Drug Administration (FDA) for legal use in animals or humans.[5] Hebert allegedly provided syringes with suspended dermorphin to horse trainers and instructed the trainers how and when to inject the racehorses.[6] The syringes were either unlabeled or had a hand-written "1."[7] Hebert allegedly obtained the dermorphin from EPC, which offered it for sale as an animal drug.[8] For at least part of the conspiracy, when EPC sent the synthetic dermorphin to Hebert, it falsely relabeled the dermorphin product that it had received from a chemical supply company to make it appear that the dermorphin was a drug compounded by EPC pursuant to veterinarian prescription.[9]

On February 7, 2017, the government indicted EPC on three counts, and Hebert on four counts.[10] The first count of the indictment alleges that EPC and Hebert conspired (1) to introduce and deliver adulterated and misbranded prescription animal drugs in interstate commerce with the intention of defrauding and misleading the FDA, the Louisiana Racing Commission, and the Louisiana State Police in violation of the FDCA, 21 U.S.C. § 331(a); (2) to receive adulterated or misbranded drugs in interstate commerce and deliver them for pay, *id.* § 331(c); (3) to alter, mutilate, obliterate, or remove the drug's labeling, and thereby, made the drug adulterated or misbranded, *id.* § 331(k); and (4) to do these actions with the intent to defraud or mislead, *id.* § 333(a)(2). The indictment alleges that the dermorphin was adulterated as defined at 21 U.S.C. §§

[4] *Id.* ¶ D.4.

[5] *Id.* ¶ A.7.D.

[6] *Id.* ¶ D.6.

[7] *Id.* ¶ D.5.

[8] *Id.* ¶ D.1.

[9] *Id.* ¶¶ D.1-2.

[10] *See generally id.*

351(a)(5)[11] and 360b,[12] and that they were misbranded as defined at 21 U.S.C. § 352(a),[13] (b),[14] (c),[15] and (f)(1).[16] The second and fourth counts indict EPC for introducing adulterated or misbranded drugs into interstate commerce with the intent to defraud and mislead, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The third and fifth counts indict Hebert for receiving adulterated or misbranded drugs in interstate commerce, and delivering or proffering to deliver those drugs for pay with the intent to defraud and mislead, in violation of 21 U.S.C. §§ 331(c) and 333(a)(2). The sixth count indicts Hebert for misbranding a drug, while holding it for sale after shipment in interstate commerce, with the intent to defraud and mislead, in violation of 21 U.S.C. §§ 331(k) and 333(a)(2). Both EPC and Hebert argue that the indictment should be dismissed because the FDCA does not govern veterinary compounding or compounded animal drugs.[17] In its opposition, the government argues that compounded animal drugs are considered new drugs under the FDCA, and subject to the FDCA adulteration and misbranding provisions.[18]

[11] "A drug or device shall be deemed to be adulterated…if it is a new animal drug which is unsafe within the meaning of section 360b of this title." 21 U.S.C. § 351(a)(5). Under § 360b,

[12] This section defines what is an unsafe new animal drug.

[13] "A drug or device shall be deemed to be misbranded [if] its labeling is false or misleading in any particular. …" *Id.* § 352(a)(1).

[14] "A drug or device shall be deemed to be misbranded…[i]f in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count…" *Id.* § 352(b).

[15] "A drug or device shall be deemed to be misbranded [if] any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness … and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." *Id.* § 352(c).

[16] "A drug or device shall be deemed to be misbranded [unless] its labeling bears (1) adequate directions for use ." *Id.* § 352(f)(1).

[17] EPC's Memo. in Support (36-1); Hebert's Memo. in Support (Rec. Doc. 37-1) (adopting EPC's arguments).

[18] Memo. in Opposition (Rec. Doc. 44).

II. STANDARD OF REVIEW

A defendant may move to dismiss the indictment by a pretrial motion under Rule 12 of the Federal Rules of Criminal Procedure. When reviewing a pretrial motion to dismiss an indictment, the court must consider all of the allegations in the indictment as true and may only grant the motion to dismiss when the dismissal hinges on a question of law. *United States v. Fontenot*, 665 F.3d 640, 644 (5th Cir. 2011). The court may not dismiss an indictment based on the sufficiency of evidence supporting the allegations in the indictment. *Costello v. United States*, 350 U.S. 359, 364 (1956). However, the court may consider the legal sufficiency of uncontested facts and the correct statutory interpretation. *United States v. Flores*, 404 F.3d 320, 326 (5th Cir. 2005). If the court finds that after resolving the questions of law, the defendant could not be found criminally liable; the court should grant the motion to dismiss.

III. LAW & ANALYSIS

The indictment alleges that EPC and Hebert introduced adulterated and/or misbranded drugs into interstate commerce; that Hebert received adulterated and/or misbranded drugs in interstate commerce and then delivered those drugs for pay; and that Hebert altered or removed the drug label, making it adulterated or misbranded. For each of the charges against EPC and Hebert, the government must be able to show that the dermorphin was adulterated or misbranded under the FDCA. Under 21 U.S.C. § 351(a)(5), an animal drug is "adulterated" if it is "*a new animal drug* which is unsafe within the meaning of section 360b[.]" (emphasis added). The definition of "drug" under the FDCA includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and … articles (other than food) intended to affect the structure or any function of the body of man or other animals[.]" 21 U.S.C.A. § 321(g)(1)(B)-(C). Under a plain reading of this definition, dermorphin would be a drug because it allegedly affected the function of the racehorses. A new animal drug is "any

drug intended for use for animals other than man, … the composition of which … is not generally recognized, among experts … as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof[.]" *Id.* § 321(v)(1). Under § 360b, a new animal drug is unsafe unless it is approved by the FDA or meets a listed exception. *Id.* § 360b.

A drug can be misbranded under the FDCA under several circumstances, including: "[i]f its labeling is false or misleading in any particular[,]" *id.* § 352(a)(1); if while in package form it does not bear "a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count[,]" *id.* § 352(b); "[i]f any word, statement, or other information required … to appear on the label … is not prominently [and conspicuously] placed thereon[,]" *id.* § 352(c); or if its labeling does not bear "adequate directions for use[,]" *id.* § 352(f)(1). Section 352 also allows the FDA to promulgate regulations exempting certain drugs from these provisions. *See id.* The FDCA misbranding provision applies to FDA-approved drugs and new drugs. *See, e.g.*, 21 C.F.R. § 201.100-129 (exempting certain approved and new drugs from the FDCA's labeling requirements for adequate directions for use).

A. Veterinary Compounding Under the FDCA

The defendants makes the general argument that veterinary drug compounding is exempt from the FDCA and that compounded animal drugs cannot be considered adulterated or misbranded because they are not "new animal drugs." While not addressing whether the drugs in the instant case were actually compounded, the government argues compounded animal drugs are subject to the FDCA as "new animal drugs."[19] "Drug compounding is the process by which a

[19] Memo. in Opposition (Rec. Doc. 44).

pharmacist combines or alters drug ingredients according to a doctor's prescription to create a medication to meet the unique needs of an individual human or animal patient." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 387 (5th Cir. 2008) (citing *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002)). EPC argues that "[a]s a veterinary compounder [it] is not subject to any requirements set forth in the FDCA as it is not dealing with a 'new animal drug.'"[20] Hebert argues that "[t]he drugs which he received from [EPC] are not subject to the FDCA because the FDCA does not apply to drugs compounded by veterinary compounding pharmacies."[21] To the extent that the defendants argue that an entity which holds itself out as a veterinary compounder is exempt from compliance with the FDCA, this argument fails. The FDCA's application hinges on the substance in question not who created the substance. *See Med. Ctr. Pharmacy*, 536 F.3d at 395. Therefore, if a compounded animal drug exception existed under the FDCA, the exception would only apply when the drug in question was actually compounded.

The indictment makes no allegations that EPC compounded the dermorphin. When explaining what EPC is, the indictment alleges that "EPC was advertised as a compounding pharmacy engaged in the business of selling compounded drugs, including dermorphin, to licensed veterinarians."[22] Yet, when describing the criminal actions that EPC took to violate the FDCA, the indictment asserts that EPC "falsely *relabeled* the [dermorphin that it received from a chemical supply company] with labeling that made it appear that the product was a compounded drug,"[23] and that Hebert and his employees "created or caused to be created a liquid suspension

[20] EPC's Memo. in Support (Rec. Doc. 36-1), p. 10.

[21] Hebert's Memo. in Support (Rec. Doc. 37-1), p. 1.

[22] Indictment (Rec. Doc. 2), ¶ A.2.

[23] *Id.* ¶ D.2. (emphasis added).

out of powdered dermorphin."[24] Based on the indictment, EPC did not compound the dermorphin it sold to Hebert, and therefore, even if the defendants' argument was successful, it would not lead the court to dismiss the indictment.[25]

Even if the court assumed, as the government does in its opposition, that EPC compounded the dermorphin, the defendants' argument would fail. The government relies heavily on the Fifth Circuit's opinion and reasoning in *Medical Center Pharmacy,* 536 F.3d 383, to refute the defendants' argument,[26] and this court agrees that *Medical Center Pharmacy* is binding precedent for whether compounded animal drugs are subject to the FDCA. Under this precedent, "compounded drugs are 'new animal drugs' within the meaning of § 321(v)(1) of the FDCA." *Med. Ctr. Pharmacy*, 536 F.3d at 408. The Fifth Circuit arrived at this conclusion by reading the FDCA in conjunction with the Animal Medicinal Drug Use Clarification Act ("AMDUCA"), Pub. L. No. 103–396, 108 Stat. 4153 (codified as amended at 21 U.S.C. § 360b(a)(4), (5)). AMDUCA amended § 360b to include two specific exceptions that would allow some compounded animal drugs to be exempt from the FDA approval process and to not be considered "unsafe" under § 360b or "adulterated" under § 351(a)(5).

These exceptions establish

> that if a new animal drug is approved for one animal use, it can be used for a different unapproved use (i.e., compounded), and … that if a new drug is approved for human use, it can be used for a different unapproved animal use (i.e., compounded). In both cases, the drug must be used pursuant to the [lawful] order of a licensed veterinarian and is subject to the FDA's discretionary finding that it poses a risk to public health.

[24] *Id.* ¶ D.3.

[25] While Hebert's suspension of the dermorphin seems to be the most likely example of compounding in the indictment, neither defendant alleges that Hebert compounded the dermorphin. If Hebert had raised this issue, it would have been unsuccessful for the reasons more fully explained below.

[26] Memo. in Opposition (Rec. Doc. 44), pp. 13-14.

Med. Ctr. Pharmacy, 536 F.3d at 408 (citing 21 U.S.C. §§ 360b(a)(4), (5)). The Fifth Circuit concluded that unless compounded drugs were considered new animal drugs, AMDUCA's amendments would be superfluous. *Id.* While the Fifth Circuit came to this conclusion regarding the FDA's ability to regulate compounded drugs in a civil context, a statute must be interpreted consistently whether it is applied civilly or criminally. *See Leocal v. Ashcroft*, 543 U.S. 1, 12 n.8 (2004). Therefore, this court is bound by this statutory interpretation.

EPC and Hebert argue that the Fifth Circuit's ruling in *Medical Center Pharmacy* is distinguishable from the instant case for four reasons: (1) as a civil action brought under the Administrative Procedure Act, its holding is inapplicable in a criminal context; (2) the ruling goes toward the FDA's discretionary authority but not criminal behavior; (3) the opinion acknowledges that Congress did not intend for all compounded drugs to go through a new drug approval process; and (4) the ruling was based on an assumption that compounded drugs were created from FDA approved substances.[27] The court is not persuaded by these arguments.

First, as previously discussed, a statute must be interpreted consistently in a civil and criminal context, and therefore, the Fifth Circuit's interpretation in a civil case is binding on a district court in a criminal case. *See Leocal*, 543 U.S. at 12 n.8. Second, the defendants' argument that *Medical Center Pharmacy*'s ruling only goes toward the FDA's discretionary authority does not acknowledge that the Fifth Circuit's plain interpretation of the statute is that "compounded drugs are 'new animal drugs' within the meaning of § 321(v)(1) of the FDCA." 536 F.3d at 408. The regulatory authority acknowledged by the Court of Appeals was that the FDA can create additional regulations for a compounded drug, but it was not whether compounded drugs are new drugs under the FDCA. *Id.* (citing 21 U.S.C. § 360b(a)(4), (5)).

[27] Memo. in Support (Rec. Doc. 36-1), pp. 6-7.

The defendants' third argument that Congress intended to exempt compounded drugs from the FDA approval process is based on selectively pulled quotes from the *Medical Center Pharmacy* opinion. The Fifth Circuit discussed the tension between considering compounded drugs new drugs subject to FDA approval requirements and the desire to allow compounding to exist. *See id.* at 398. The court resolved this tension by relying on two amendments to the FDCA, the Food and Drug Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 11 Stat. 2296 (codified as amended at 21 U.S.C. § 353a (2000)) and AMDUCA. The FDAMA exempted certain compounded human drugs, and AMDUCA exempted certain compounded animal drugs from the onerous FDA approval process. *Id.* at 405-06, 408-09. The Fifth Circuit reasoned that these amendments, read in conjunction with the definition of new drug, led to the logical conclusion that compounded drugs are new drugs subject to the FDCA, but they are not considered adulterated drugs if they meet the amendments' criteria. *Id.*

Applying the Fifth Circuit's opinion to this case, regardless of whether the dermorphin was compounded, it would be subject to the FDCA and be considered a new animal drug because dermorphin allegedly has not been "recognized, among experts … as safe and effective for use" with racehorses. *See* 21 U.S.C. § 321(v)(1). Thus, for the dermorphin to not be adulterated under 21 U.S.C. § 351(a)(5), it would need to be approved by the FDA or meet a § 360b exception. To meet AMDUCA's § 360b exceptions for certain compounded animal drugs, dermorphin would need to be approved by the FDA for an animal use, 21 U.S.C. 360b(a)(4), or a human use, 21 U.S.C. § 360b(a)(5) and be used in an unapproved way; the dermorphin compound would need to be used pursuant to a lawful order of a licensed veterinarian in the context of a veterinarian-client-patient relationship;[28] and the dermorphin would need to comply

[28] *See* 21 C.F.R. § 530.3 (setting forth the parameters of a valid veterinarian-client-patient relationship).

with any applicable FDA regulations. 28 U.S.C. § 360b(4)-(5). Based on the indictment, the dermorphin would not meet an AMDUCA exception because the FDA has not approved any use of dermorphin for humans or animals.[29] Additionally, based on the facts of the indictment, EPC did not sell dermorphin to Hebert pursuant to a lawful order in the context of a veterinarian-client-patient relationship, because no prescription was given for the dermorphin and the underlying application of the drug was illegal under state law. Accordingly, based on the indictment's allegations, the dermorphin was adulterated under 21 U.S.C. § 351(a)(5).

Furthermore, based on *Medical Center Pharmacy*'s reasoning, compounded animal drugs would be subject to the misbranding provisions of the FDCA.[30] Because compounded animal drugs are "new animal drugs," compounded animal drugs are "drugs" under the FDCA. The misbranding provision of the FDCA applies to "drugs" and does not limit its application to new or approved drugs. 21 U.S.C. § 352. Accordingly, dermorphin would be subject to 21 U.S.C. § 352(a)(1), (b), (c), and (f)(1), and the defendants raise no FDA regulations which would exempt them from these requirements. Based on the indictment's allegations, the dermorphin was mislabeled or unlabeled by both EPC and Hebert, and it did not include directions for use. This would make the dermorphin misbranded.

Finally, the defendants' argument that the Fifth Circuit's ruling applies only to drugs that were compounded from already-approved FDA drugs is baseless. The Fifth Circuit's discussion of compounded animal drugs was specifically about animal drugs compounded from bulk ingredients, not animal drugs compounded from already-approved FDA drugs. *Med. Ctr.*

[29] Indictment (Rec. Doc. 1), ¶ A.7.D.

[30] The Fifth Circuit addressed whether drugs in bulk packages used to make compounded animal drugs were subject to the misbranding provisions of 21 U.S.C. § 352(f). The court concluded that because the materials were being used to create "new animal drugs," the bulk ingredients did not meet a labeling exemption found in an FDA regulation, and they were required to bear "adequate directions for use." *Med. Ctr. Pharmacy*, 536 F.3d at 407 & n.49 (citing 21 C.F.R. § 201.122). The Fifth Circuit did not address the other misbranding provisions' application to animal drugs compounded from bulk ingredients.

Pharmacy, 536 F.3d at 407. Under *Medical Center Pharmacy*, animal drugs compounded from bulk ingredients are "new animal drugs" and are adulterated unless they are FDA approved or meet a § 360b exception. *Id.*

The defendants attempt to muddle the clarity of the Fifth Circuit opinion by citing a Middle District of Florida case, FDA publications, the Drug Quality and Security Act (the "DQSA"), Pub. L. 113-54, 127 Stat. 587 (codified as amended at 21 U.S.C. § 301, *et seq.*) (2013), and a House Appropriations Report. None of the cited material leads the court to a different conclusion.

While a federal court in Florida held that the FDCA did not give the FDA the authority to enjoin the compounding of animal drugs from bulk ingredients, this court is not bound by that decision, which dismissed part of the holding of *Medical Center Pharmacy* and did not consider the impact of AMDUCA on the FDCA. *See United States v. Franck's Lab, Inc.*, 816 F. Supp. 2d 1209, 1256 (M.D. Fla. 2011), *order vacated, appeal dismissed*, No. 11-15350, 2012 WL 10234948 (11th Cir. Oct. 18, 2012). Furthermore, as argued by the government,[31] the non-binding FDA publications[32] cited by the defendants do not overrule or suggest a change to the unambiguous statutory interpretation that "compounded drugs are 'new animal drugs' within the meaning of § 321(v)(1) of the FDCA." *Med. Ctr. Pharmacy*, 536 F.3d at 408. Similarly, the passage of the DQSA does not change the definition of "new animal drugs" because the DQSA deals with human drug compounding. *See generally* 127 Stat. 587. Also, the cited House

[31] Memo. in Opposition (Rec. Doc. 44), pp. 16-17.

[32] EPC recounts a 2003 Compliance Policy Guide in which the FDA stated that it would enforce the FDCA against animal drug compounders in certain circumstances, a draft guidance entitled "Compounding Animal Drugs from Bulk Drug Substances" in which the FDA declared that all veterinary compounding falls under the purview of the FDCA, and a draft guidance entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug and Cosmetic Act" which affirmatively states that statutory provisions governing human drug compounding do not govern animal drug compounding.

Appropriations Report,[33] even if it suggested a different interpretation, does not alter *Medical Center Pharmacy*'s holding because it is not law. Accordingly, the court finds that based on Fifth Circuit precedent, the FDCA's statutory text, and the indictment itself, the government has sufficiently alleged that the dermorphin sold by EPC and subsequently resold by Hebert was an adulterated and/or misbranded new animal drug subject to the FDCA.

B. Rule of Lenity

Finally, the defendants argue that even if the FDCA allows the FDA to regulate animal compounding, the statute is ambiguous as to whether compounded animal drugs are new animal drugs that can be considered adulterated or misbranded. Based on this ambiguity, they argue that the indictment should be dismissed under the rule of lenity. "The rule of lenity requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them." *United States v. Santos*, 553 U.S. 507, 514 (2008) (citations omitted). This rule rests on the "principle that no citizen should be held accountable for a violation of a statute whose commands are uncertain, or subjected to punishment that is not clearly prescribed." *Id.* The rule of lenity does not apply automatically if the defendant is able to articulate a different construction than the one urged by the government or if judicial authority is divided on the interpretation. *Moskal v. United States*, 498 U.S. 103, 108 (1990) (citations omitted). The rule should be applied only when "a reasonable doubt persists about a statute's intended scope even after resort to 'the language and structure, legislative history, and motivating policies' of the statute." *Id.* (citations omitted).

Based on the language, structure, legislative history, and motivating policies of the FDCA and AMDUCA, as discussed by the Fifth Circuit in *Medical Center Pharmacy*, the rule of lenity does not apply. When the FDCA and AMDUCA are read in conjunction, they

[33] H.R. Rep. No. 114-531, at 66 (2016).

unambiguously include compounded animal drugs within the definition of new animal drugs, making compounded animal drugs subject to the FDCA. *Med. Ctr. Pharmacy*, 536 F.3d at 408.

IV. CONCLUSION

To the extent that the indictment does not allege that EPC compounded the drugs involved in the case, the defendants' argument is irrelevant and would not subject the indictment to a Rule 12 dismissal. To the extent that EPC compounded the relevant drugs, those drugs are subject to the FDCA and may be considered adulterated or misbranded based on the facts of the indictment. Accordingly, for the reasons explained above,

IT IS ORDERED that the defendants' Motions to Dismiss the Indictment (Rec. Docs. 36, 37) are **DENIED**.

Shreveport, Louisiana, this 6th day of July, 2017.

DONALD E. WALTER
UNITED STATES DISTRICT JUDGE